

Application No. 09/889,687

2

The 35 USC 112, ¶2 rejection:

Claims 12-22 were rejected under 35 USC 112, ¶2 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regard as the invention.

In particular, the Examiner objected to:

(A) The term "substitution" or "substituted" in all occurrences in which it appears where "it fails to articulate by chemical name, structural formula, ... requisite to identifying the compound of matter claimed." Applicants respectfully disagree.

The term "substituted" occurs in the claims in question with regard to substituted alkyl, substituted alkenyl, substituted alkynyl, substituted cycloalkyl and substituted aryl. Applicants assert that there is nothing indefinite in the term "substituted" as it is used in the context of these five groups. A person of ordinary skill in the art would readily understand the meaning of "substituted" as used in the present invention without further qualification or explanation. Applicants concede that the term "substituted" is not explicitly defined in the application, and this is not accidental because the term is used with its conventional chemical meaning, which is the meaning appropriate to an application addressed to the chemical/pharmaceutical art. In fact, the term "substituted" is used in the present application in a succinct and definite manner that is routinely observed in the claims of patents issuing in the similar chemical/pharmaceutical art. By way of example only, Applicants refer the Examiner to US Patent Nos. 6,605,725, 6,552,013, 5,453,495 and 6,596,744 that include the use of the same terminology in the claims. Furthermore, such patents were merely representative of recently granted patents, and a recent search identified over 77,000 US patents that include the same terms in the claims.

Applicants note that the terms "alkenyl" and "substituted alkenyl" occur twice in a row in Claim 12, and that in the second instance, these terms should read "alkynyl" and "substituted alkynyl", respectively. Claim 12 has been amended accordingly to correct this minor clerical error.

(B) "The absence of the specific derivatizations to the [term] "sugar analogue" core or language to describe the structural modifications or the chemical names "sugar analogue" in all occurrences" and the derivatives cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated.

The phrase "sugar analogue" are in claims 19 and 20. Claims 19 and 20 having been canceled in the present Response, the objection as to this phrase is rendered moot.

(C) The phrase "universal monosaccharide" is not defined in the claim and the specification does not allow one to be apprised of the scope of the invention.

Applicants have replaced the phrase "universal monosaccharide" in claim 12 with the phrase "an orthogonally protected monosaccharide." Support for this phrase is found in the specification as filed on page 1 (lines 6-7). Furthermore, discussions of orthogonally protected monosaccharides, orthogonal protection, orthogonally-protected saccharide and orthogonally protected functional groups are found generally throughout the application.

(D) The phrase "may only be" or "can be" in Claim 12 renders the claim indefinite. The Examiner suggested the use of the term "is" in place of "may" or "can."

Application No. 09/889,687

3

In Claim 12, the terms "may only be" and "can be" has been replaced with the term "is". Applicants thank the Examiner for the suggestion.

(E) The term "sets" of protecting group are not defined and renders the claims in which it appears indefinite.

In Claims 14 and 16, the terms "set" and "sets" refer to the protecting group set(s) and the claims have been amended to clarify the terms by adding the phrase "as herein defined."

(F) The term "amongst" is superfluous and should be deleted.

The term "amongst" has been deleted from Claim 16, rendering the objection moot.

(G) Claim 17 is rejected as being incomplete for omitting essential steps of the synthesis; The Examiner suggests that the claim be amended.

Claim 17 has been amended to clearly define the process step of "glycosylating" the molecule with a building block of Claim 12. Claim 17 having been amended, the rejection is moot as to this Claim.

The 35 USC 101 rejection:

Claim 17 has been amended to clearly define the step of "glycosylating" the molecule with a building block of Claim 12. Claims 18, 21 and 22, which are directly dependent on Claim 17, are now definite in view of amended Claim 17. Applicants assert that the rejection is moot as to Claim 17, 18, 21, and 22.

The 35 USC 102 rejection:

The Examiner rejected Claims 12-22 under 35 USC 102(b) as being anticipated by Yamada et al (EP 578,112). Applicants submit that the compounds in Yamada et al are not orthogonally protected monosaccharide building blocks as claimed in the present invention. As defined in the present application (page 2, lines 19-20) and as supported generally throughout the application, "orthogonal protection" of functional groups or "the principle of orthogonal stability requires that only those protecting functions should be used that can be cleaved under different reaction conditions without affecting the other functions present." Yamada et al disclose and claim compounds I and II, for example, having two or more identical OBz (O-benzyl) groups on a single disaccharide that are not considered to be independently stable with regard to the selective removal of a single OBz group without cleaving the other OBz protecting groups. That is, the disaccharide compounds are not orthogonally protected because a specific protecting group of a hydroxyl (OH) group, such as two or more Bz groups as protecting groups for two or more OH groups, cannot be selectively cleaved without affecting the other hydroxyl groups that is also protected by another Bz group.

Claim 12, as presently amended, further defines that the orthogonal groups B, C, D, and E of the present invention are different and can be cleaved orthogonally in any order "such that the cleavage conditions do not compromise the stability of the other protecting or functional groups on the monosaccharide building block."

Withdrawal of the rejection is respectfully requested.

Application No. 09/889,687

4

State of the Art References:

The Examiner cited Kahne et al (US Patent 6,040,433) and Wong et al (US Patent 6,538,117). Applicants note that the cited references are not considered to be pertinent to the present invention.

Conclusion

For the reasons given above, Applicants submit that the claims as presently amended are definite under 35 USC 112, ¶2, are patentable processes under 35 USC 101, and are not unpatentable under 35 USC 102(b) over Yamada et al.

Re-examination and allowance of the claims are respectfully requested.

Respectfully submitted,



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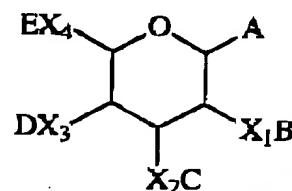
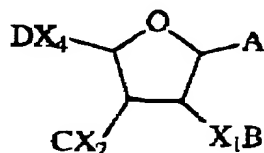
Application No. 09/889,687

5

CLAIM AMENDMENT

1-11. (Canceled)

12. (Currently amended): ~~A universal~~ An orthogonally protected monosaccharide building block of General Formula I or General Formula II



in which,

A is a leaving group selected from the group consisting of -SR; where R is alkyl, substituted alkyl, alkenyl, substituted alkenyl, ~~alkenyl, substituted alkenyl, alkynyl, substituted alkynyl,~~ cycloalkyl, substituted cycloalkyl, aryl, substituted aryl, halogen; trichloroacetimidoyl-; sulfoxide; and -O- alkenyl;

X₁, X₂, and X₃ are independently selected from H, O, N, or N₃, with the proviso that only one of X₁, X₂, and X₃ ~~may be~~ is H, N or N₃ in any molecule;

X₄ is H, -CH₂O, -CH₂N, -CH₃, -CH₂N₃ or -COO-, with the proviso that X₄ ~~may only be~~ is H, -CH₂N, -CH₃ or CH₂N₃ when none of X₁ to X₃ is H; and

B, C, D and E are different, and are selected from protecting groups which can be cleaved orthogonally in any order, such that the cleavage conditions do not compromise the stability of the other protecting or functional groups on the monosaccharide building block.

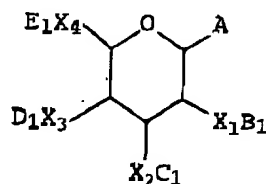
and in which,

B or C or D or E is absent if the corresponding X₁ to X₃ is H or N₃, or if the corresponding X₄ is H, -CH₃ or -CH₂N₃.

Application No. 09/889,687

6

13. (Previously presented): A monosaccharide building block according to claim 12, which is a compound of General Formula III

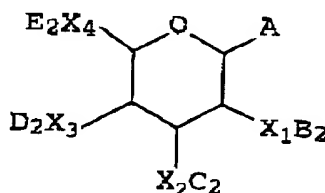


III

in which,

A, X₁, X₂, X₃ and X₄ are as defined for General Formulae I and II, and B₁, C₁, D, and E₁ are orthogonal carbohydrate protecting groups selected from protecting group sets 1, 2, 6 and 8 as herein defined.

14. (Currently amended): A monosaccharide building block according to claim 12, which is a compound of General Formula IV



IV

in which,

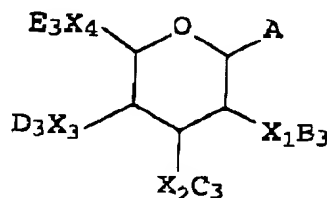
A, X₁, X₂, X₃ and X₄ are as defined for General Formulae I and II, and B₂, C₂, D₂ and E₂ are selected from the members of protecting group set 1, and in themselves constitute an orthogonal set, as defined herein.

15. (Previously presented): A monosaccharide building block according to claim 14, in which the members of protecting group set 1 are levanoyl, chloroacetate, *p*-methoxybenzyloxycarbonyl and 2-trimethylsilylethylcarbonate.

Application No. 09/889,687

7

16. (Currently amended): A monosaccharide building block according to claim 12, which is a compound of General Formula V



V

in which,

A, X₁, X₂, X₃ and X₄ are as defined for General Formulae I and II, and B₃, C₃, D₃ and E₃ are an orthogonal set of protecting groups selected from amongst the members of set 1, as herein defined and from the remaining orthogonal sets as herein defined.

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17. (Currently amended): A method of synthesis of a molecule selected from the group consisting of glycoconjugates of non-carbohydrate molecules, neo-glycoconjugates and oligosaccharides, comprising the step of using glycosylating the molecule with a monosaccharide building block according to claim 12.
18. (Previously presented): A method according to claim 17, in which the molecule comprises one or more compounds in which substituents are linked to a pyranose or furanose ring.
19. (Canceled)
20. (Canceled)
21. (Previously presented): A method according to claim 17, in which the synthesis is carried out in solution.
22. (Previously presented): A method according to claim 17, in which the synthesis is carried out on a solid-phase support.